

4-27-05
JC02 Rec'd PCT/US 26 APR 2005

EL 984915892 US

PCT

#3 PATENTS

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re: Sandrine, *et al.*) Examiner: Unassigned
Serial No.: 10/524,318)
Filed: February 9, 2005) Art Unit: Unassigned
For: **Galenic Form for Colonic Delivery**) Docket No.: L108 1010.1
of Active Ingredients)
:

INFORMATION DISCLOSURE STATEMENT

Commissioner for Patents
P.O. Box 1450
Alexandria, VA 22313-1450

Sir:

Applicants hereby voluntarily disclose seventeen (17) references listed on the attached Form PTO-SB-08, (2 pages) to the Commissioner for Patents. Copies of the references listed on Applicants' Form PTO-SB-08 are enclosed herewith.

Applicants reserve the right to establish the patentability of the claimed invention over any of the listed information should they be applied as references, and/or to prove that some of the cited information may not be prior art, and/or to prove that some of the cited information may not be enabling for the teachings they purport to offer.

This statement should not be construed as a representation that a search has been made, or that the information cited herewith is material, or that there does not exist information more material to the examination of the present Application. The Examiner is specifically requested not to rely solely on the information submitted herein. On the contrary, the Examiner is requested to conduct an independent and thorough review of all available information, and to form independent opinions as to its significance.

It is respectfully requested that the Examiner initial and return copies of the enclosed PTO-SB-08 and to indicate in the official file wrapper of the above-identified patent application that each item of the cited information has been considered.

Respectfully submitted,

Date: 4/26/05



David S. Bradin
Attorney for Applicants
Registration No. 37,783

Docket: L108 1010.1

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Substitute for form 1449/PTO

**INFORMATION DISCLOSURE
STATEMENT BY APPLICANT**
(Use as many sheets as necessary)

Sheet 1 of 2

Complete if Known

Application Number	10/524,318
Filing Date	02-09-2005
First Named Inventor	Sandrine, <i>et al.</i>
Art Unit	Unassigned
Examiner Name	Unassigned

Attorney Docket Number

L108 1010.1

U.S. PATENT DOCUMENTS

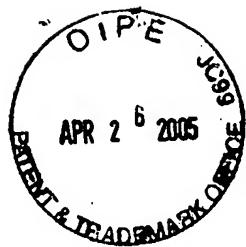
Examiner Initials*	Cite No. ¹	Document Number Number-Kind Code ² (<i>if known</i>)	Publication Date MM-DD-YYYY	Name of Patentee or Applicant of Cited Document	Pages, Columns, Lines, Where Relevant Passages or Relevant Figures Appear
		3,959,457	05-25-1976	Speaker et al.	

FOREIGN PATENT DOCUMENTS

Examiner Initials*	Cite No. ¹	Foreign Patent Document Country Code ³ Number ⁴ Kind Code ⁵ (<i>if known</i>)	Publication Date MM-DD-YYYY	Name of Patentee or Applicant of Cited Document	Pages, Columns, Lines, Where Relevant Passages Or Relevant Figures Appear	T ⁶
	F1	EP 0 480 729 A1	04-15-1992	Korea Research Inst. Of Chem. Technology		
	F2	EP 0 454 044 A2	10-30-1991	Hoechst Aktiengesellschaft		
	F3	EP 0 338 499 A2	10-25-1989	Nabisco Brands, Inc.		
	F4	EP 0 273 823 A1	07-06-1988	Mero Roussellotsatia, Scoiété anonyme		
	F5	EP 0 213 303 A2	03-11-1987	Magnus, Ekman Bo Mänstigen 9		
	F6	WO 93/13757	01-18-1993	Alfa-Tec-Pharma, GMBH		
	F7	WO 92/00732	01-23-1992	Kabi Pharmacia AB		

Examiner Signature		Date Considered	
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*EXAMINER: Initial if reference considered, whether or not citation is in conformance with MPEP 609. Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant.¹ Applicant's unique citation designation number (optional). ²See Kinds Codes of USPTO Patent Documents at www.uspto.gov or MPEP 901.04. ³ Enter Office that issued the document, by the two-letter code (WIPO Standard ST.3). ⁴For Japanese patent documents, the indication of the year of the reign of the Emperor must proceed the serial number of the patent document. ⁵Kind of document by the appropriate symbols as indicated on the document under WIPO Standard ST.16 if possible. ⁶Applicant is to place a check mark here if English language Translation is attached. This collection of information is required by 37 CFR 1.97 and 1.98. The information is required to obtain or retain a benefit by the public which is to file (and by the USPTO to process) an application. Confidentiality is governed by 35 U.S.C. 122 and 27 CFR 1.14. This collection is estimated to take 2 hours to complete, including gathering, preparing, and submitting the completed application form to the USPTO. Time will vary depending upon the individual case. Any comments on the amount of time you require to complete this form and/or suggestions for reducing this burden, should be sent to the Chief Information Officer, U.S. Patent and Trademark Office, P.O. Box 1450, Alexandria, VA 22313-1450. DO NOT SEND FEES OR COMPLETED FORMS TO THIS ADDRESS. SEND TO: Commissioner for Patents, P.O. Box 1450, Alexandria, VA 22313-1450. If you need assistance in completing the form, call 1-800-PTO-9199 (1-800-786-9199) and select option 2.



Patents

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re application of:)
Bour-Geois SANDRINE et al.) Examiner: ***
Serial No.: 10/524,318) Art Unit: ***
Filed: February 9, 2005)
For: Galenic Form for Colonic Delivery)
of Active Ingredients)

CERTIFICATE OF EXPRESS MAILING

Box: Amendment/IDS
Commissioner for Patents
P.O. Box 1450
Alexandria, VA 22313-1450

Enclosed for filing in the above case are the following documents:

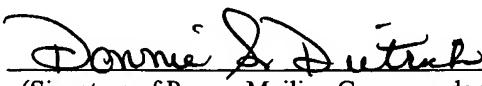
I hereby certify that the Information Disclosure Statement and all supporting documents are being deposited with the U.S. Postal Service.

Womble Carlyle Sandridge & Rice, PLLC
P.O. Box 7037
Atlanta, GA 30357-0037
(404) 879-2423 (Telephone)
(404) 879-2923 (Facsimile)

Docket No.: L108 1010.1 (53598.0002.1)

I hereby certify that all correspondences listed above are being deposited for delivery to the above addressee, with the United States Postal Service under 37 CFR 1.10 on April 26, 2005. The envelope has been given U.S. Postal Service "Express Mail Post Office To Addressee" Package #EL 984 915 892 US.

Donnie S. Dietrich
(Printed Name of Person Mailing Correspondence)


(Signature of Person Mailing Correspondence)



APR 26 2005

PTO/SB/08B (08-03)

Approved for use through 7/31/2006. OMB 0651-0031

U.S. Patent and Trademark Office; U.S. DEPARTMENT OF COMMERCE

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<p>Substitute for form 1449/PTO</p> <p>INFORMATION DISCLOSURE STATEMENT BY APPLICANT</p> <p><i>(Use as many sheets as necessary)</i></p>				Complete if Known			
				Application Number		10/524,318	
				Filing Date		02-09-2005	
				First Named Inventor		Sandrine, <i>et al.</i>	
				Art Unit		Unassigned	
				Examiner Name		Unassigned	
Sheet	2	of	2	Attorney Docket Number		L108 1010.1	

NON PATENT LITERATURE DOCUMENTS				
Examiner Initials*	Cite No. ¹	Include name of the author (in CAPITAL LETTERS), title of the article (when appropriate), title of the item (book, magazine, journal, serial, symposium, catalog, etc.), date, page(s), volume-issue number(s), publisher, city and/or county where published.		
		AYDIN, Z. AND AKBUGA, J., "Preparation and evaluation of pectin beads", <i>Inter. J. Pharm.</i> , v. 137, p133-136, 1996.		
		KRISHNAIAH, Y.S.R., et al., "Evaluation of guar gum as compression coat for drug targeting to colon", <i>Inter. J. Pharm.</i> , v171, p137-146, 1998.		
		MILOJEVIC, S., et al., "Amylose as a coating for drug delivery to the colon: Preparation and in vitro evaluation using 5-aminosalicylic acid pellets", <i>J. Cont. Release</i> , v37, p75-84, 1996.		
		MUNJERI, O., et al., "Hydrogel beads based on amidated pectins for colon-specific drug delivery: the role of chitosan in modifying drug release", <i>J. Cont. Release</i> , v46, p273-278, 1997.		
		RUBINSTEIN, A., et al., "In Vitro Evaluation of Calcium Pectinate: A Potential Colon-Specific Drug Delivery Carrier", <i>Pharm. Res.</i> , v.10:2, n258-263. 1993.		
		RUBINSTEIN, A., et al., "Colonic Drug Delivery: Enhanced Release of Indomethacin from Cross-Linked Chondroitin matrix in Rat Cecal Content" <i>Pharm. Res.</i> , v9:2, n276-278. 1992.		
		SRIAMORNSAK, P., "Investigation of pectin as a carrier for oral delivery of proteins using calcium pectinate gel beads", <i>Inter. J. Pharm.</i> , v169, n213-220. 1998.		
		SRIAMORNSAK, P., "Effect of calcium concentration, hardening agent and drying condition on release characteristics of oral proteins from calcium pectinate gel beads", <i>Eur. J. Pharm. Sci.</i> , v8, p221-227, 1999.		
		WAKERLY, Z., et al., "Pectin/Ethylcellulose Film Coating Formulations for colonic Drug Delivery", <i>Pharm. Res.</i> , v13:8, n1210-1212. 1996		

Examiner Signature		Date Considered	
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¹Applicant's unique citation designation number (optional). ²Applicant is to place a check mark here if English language Translation is attached. This collection of information is required by 37 CFR 1.98. The information is required to obtain or retain a benefit by the public which is to file (and by the USPTO to process) an application. Confidentiality is governed by 35 U.S.C. 122 and 37 CFR 1.14. This collection is estimated to take 2 hours to complete, including gathering, preparing, and submitting the completed application form to the USPTO. Time will vary depending upon the individual case. Any comments on the amount of time you require to complete this form and/or suggestions for reducing this burden, should be sent to the Chief Information Officer, U.S. Patent and Trademark Office, P.O. Box 1450, Alexandria, VA 22313-1450. DO NOT SEND FEES OR COMPLETED FORMS TO THIS ADDRESS. SEND TO: Commissioner for Patents, P.O. Box 1450, Alexandria, VA 22313-1450.

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